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ART UNIT	**PAPER NUMBER**
1635	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/536,560	BENTWICH, ITZHAK	
	Examiner	Art Unit	
	DANA SHIN	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 May 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21-48 and 50-55* is/are pending in the application.

4a) Of the above claim(s) *35-48,51,54 and 55* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21-34,50,52 and 53* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application/Amendment/Claims

This Office action is in response to the communications filed on May 11, 2010.

Currently, claims 21-48 and 50-55 are pending in the instant application. Claims 35-48, 51, and 54-55 have been withdrawn from further examination as being drawn to a non-elected invention. Accordingly, claims 21-34, 50, and 52-53 are under examination on the merits in the instant case.

The following rejections are either newly applied or are reiterated and are the only rejections and/or objections presently applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Response to Arguments and Amendments

Withdrawn Rejections

Any rejections not repeated in this Office action are hereby withdrawn.

Maintained Objections/Rejections

Priority

The benefit of a filing date prior to PCT/IL03/00998 for claims 21-34, 50, and 52-53 remains denied for the reasons of record as set forth in the Office action mailed on January 6, 2010 and for the reasons stated below.

Applicant's arguments filed on May 11, 2010 have been fully considered but they are not persuasive. Applicant argues that the priority denial was "solely" based on the lack of disclosure for SEQ ID NO:2079, which is not claimed in the genus claims. Contrary to applicant's argument, the priority denial is not "solely" on the basis of SEQ ID NO:2079. See page 3 of the last Office action: "none discloses the claimed molecule structure, let alone SEQ ID NO:2079." Hence, the Office action states that no application filed prior to PCT/IL03/00998 discloses the "structure" including SEQ ID NO:2079. As applicant must be aware, the claims recite a number of different structural requirements, including but not limited to SEQ ID NO:2079, "15-24 nucleotides", "50-131 nucleotides", "14-71 nucleotides", "3-19 nucleotides", "18-24 nucleotides", "50-120 nucleotides", "intervening loop", "30.8% complementarity", "40.9% complementarity", and so forth. As indicated in the last Office action, examiner was not able to locate all of the required structural limitations recited in the claims in any of the applications filed prior to PCT/IL03/00998 and thus it was deemed that PCT/IL03/00998 was the first earlier-filed application that provides adequate description for the claimed structure including SEQ ID NO:2079. Applicant has not pointed out any passages, pages, and lines that supposedly provide the instantly claimed structural limitations in an application preceding PCT/IL03/00998. Hence, the priority denial remains effective such that the PCT/IL03/00998 filing date remains as the effective filing date for claims 21-34, 50, and 52-53.

Claim Rejections - 35 USC § 112

Claims 21-34, 50, and 52-53 remain rejected under 35 U.S.C. 112, second paragraph as being indefinite for the reasons of record as set forth in the Office action mailed on January 6, 2010 and for the reasons stated below.

Applicant's arguments filed on May 11, 2010 have been fully considered but they are not persuasive. Applicant argues that the claims particularly point out the subject matter because the claim language is not ambiguous. In particular, applicant states that the "second viral nucleic acid" includes the "first viral nucleic acid" and that viral genomic sequences comprises both the second (hairpin precursor) and the first (miRNA) sequences, and therefore the recitation of the "second viral nucleic acid" when the claims are drawn to a "first viral nucleic acid" reduces the scope of the claims by requiring that the first nucleic acid be included within the second nucleic acid. Contrary to applicant's argument that the recitation of the "second" nucleic acid more specifically defines the scope of the claims and the nature of the subject matter, it is found that the recitation of the "second" nucleic acid does not help further define the structure of the "claimed" - that is, the "first" nucleic acid - subject matter for the following reasons:

Applicant's attention is directed to the fact that the claims are drawn to an "isolated" nucleic acid of 15-24 nucleotides (the structural requirements pertaining to the "first" nucleic acid). As such, the claims are drawn to a "final" product that has been already "isolated", wherein the "final" product is 15-24 nucleotides in length. Hence, the recitation of numerous structural limitations for the precursor (the "second" nucleic acid) nucleic acid that is neither "claimed" nor "isolated" does not do anything to reduce the scope of the "claimed", "isolated", 15-24-mer nucleic acid. In addition, the claims as currently amended are not written as product-by-process claims. As such, the need to recite the second nucleic acid for the procedure/process of obtaining the first nucleic acid as explained by applicant is even less necessary, and thus the recitation of "second" nucleic acid does not add more clarity as asserted by applicant but merely adds more ambiguity to the subject matter which applicant regards as the invention. Again, the claims are product claims drawn to a single, isolated nucleic acid that is 15-24 nucleotides in

length. That is, the claims are not drawn to two nucleic acids, nor are they product-by-process claims that must require other, unclaimed elements for the sake of the "process". Hence, the recitation of second viral nucleic acid and the limitations thereof imparts ambiguity, thereby rendering the claims indefinite. Accordingly, this rejection is maintained.

Claim Rejections - 35 USC § 102

Claims 21-22, 33-34, 50, and 52 remain rejected under 35 U.S.C. 102(e) as being anticipated by Khvorova et al. for the reasons of record as set forth in the Office action mailed on January 6, 2010 and for the reasons stated below.

Applicant's arguments filed on May 11, 2010 have been fully considered but they are not persuasive. Applicant argues that the claims are not anticipated because the nucleic acid of Khvorova et al. is not "isolated from the genome of a virus". Applicant's attention is directed to the fact that the claims are drawn to a nucleic acid of 15-24 (or 18-24) nucleotides or a complement thereof, wherein the nucleic acid is 40.9% complementary to an mRNA. Further, when the "second" nucleic acid structural limitations are taken into consideration for determining patentability of the "first" nucleic acid, the 15-24 (or 18-24) nucleotides need to be only at least 30.8% complementary or homologous to SEQ ID NO:2079 (one of the "two stem segments" of the second nucleic acid). Khvorova et al. disclosed a nucleic acid of 19 nucleotides in length (see SEQ ID NO:1360090) that is at least 72.7% homologous to SEQ ID NO:2079. Further, they taught that SEQ ID NO:1360090 is capable of inhibiting target mRNA. Hence, the nucleic acid product of Khvorova et al. is essentially identical to the claimed first nucleic acid, and thus, the nucleic acid of Khvorova et al. must be inherently "viral" and be present in a viral genome,

absent evidence to the contrary. Again, the structural and functional limitations set forth for the claimed first nucleic acid are met by SEQ ID NO:1360090 of Khvorova et al.

Note that when a rejection is based on a reference teaching a product appearing to be substantially identical to the claimed product, and when the examiner presents reasoning tending to show inherency, the burden shift to the applicant to show an unobvious difference. See MPEP 2112: "[T]he PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his [or her] claimed product. Whether the rejection is based on inherency under 35 U.S.C. 102, on *prima facie* obviousness under 35 U.S.C. 103, jointly or alternatively, the burden of proof is the same...[footnote omitted]."

Claims 21-22, 33-34, 50, and 52 remain rejected under 35 U.S.C. 102(e) as being anticipated by Usman et al. for the reasons of record as set forth in the Office action mailed on January 6, 2010 and for the reasons stated below.

Applicant's arguments filed on May 11, 2010 have been fully considered but they are not persuasive. Applicant argues that the claims are not anticipated because the nucleic acid of Usman et al. is not "isolated from the genome of a virus". Applicant's attention is directed to the fact that the claims are drawn to a nucleic acid of 15-24 (or 18-24) nucleotides or a complement thereof, wherein the nucleic acid is 40.9% complementary to an mRNA. Further, when the "second" nucleic acid structural limitations are taken into consideration for determining patentability of the "first" nucleic acid, the 15-24 (or 18-24) nucleotides need to be only at least 30.8% complementary or homologous to SEQ ID NO:2079 (one of the "two stem segments" of the second nucleic acid). Usman et al. disclosed a nucleic acid of 19 nucleotides in length (see SEQ ID NO:716) that is highly complementary to SEQ ID NO:2079. Further, they taught that

SEQ ID NO:716 is capable of inhibiting target mRNA. Hence, the nucleic acid product of Usman et al. is essentially identical to the claimed first nucleic acid, and thus, the nucleic acid of Usman et al. must be inherently "viral" and be present in a viral genome, absent evidence to the contrary. Again, the structural and functional limitations set forth for the claimed first nucleic acid are met by SEQ ID NO:716 of Usman et al. Hence, a viral genome must inherently and necessary possess the sequence of SEQ ID NO:716 of Usman et al., absent evidence to the contrary.

Note that when a rejection is based on a reference teaching a product appearing to be substantially identical to the claimed product, and when the examiner presents reasoning tending to show inherency, the burden shift to the applicant to show an unobvious difference. See MPEP 2112: "[T]he PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his [or her] claimed product. Whether the rejection is based on inherency under 35 U.S.C. 102, on *prima facie* obviousness under 35 U.S.C. 103, jointly or alternatively, the burden of proof is the same...[footnote omitted]."

Claims 21-22, 33-34, 50, and 52 remain rejected under 35 U.S.C. 102(b) as being anticipated by Stacey et al. for the reasons of record as set forth in the Office action mailed on January 6, 2010 and for the reasons stated below.

Applicant's arguments filed on May 11, 2010 have been fully considered but they are not persuasive. Applicant argues that the claims are not anticipated because the nucleic acid of Stacey et al. is not "isolated from the genome of a virus". Applicant's attention is directed to the fact that the claims are drawn to a nucleic acid of 15-24 (or 18-24) nucleotides or a complement thereof, wherein the nucleic acid is 40.9% complementary to an mRNA. Further, when the

"second" nucleic acid structural limitations are taken into consideration for determining patentability of the "first" nucleic acid, the 15-24 (or 18-24) nucleotides need to be only at least 30.8% complementary or homologous to SEQ ID NO:2079 (one of the "two stem segments" of the second nucleic acid). Stacey et al. disclosed a nucleic acid of 20 nucleotides in length (see SEQ ID NO:10) that is highly homologous to SEQ ID NO:2079. Further, they taught that SEQ ID NO:10 is capable of inhibiting target mRNA. Hence, the nucleic acid product of Stacey et al. is essentially identical to the claimed first nucleic acid, and thus, the nucleic acid of Stacey et al. must be inherently "viral" and must be present in a viral genome, absent evidence to the contrary. Again, the structural and functional limitations set forth for the claimed first nucleic acid are met by SEQ ID NO:10 of Stacey et al.

Note that when a rejection is based on a reference teaching a product appearing to be substantially identical to the claimed product, and when the examiner presents reasoning tending to show inherency, the burden shift to the applicant to show an unobvious difference. See MPEP 2112: "[T]he PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his [or her] claimed product. Whether the rejection is based on inherency under 35 U.S.C. 102, on *prima facie* obviousness under 35 U.S.C. 103, jointly or alternatively, the burden of proof is the same...[footnote omitted]."

Claims 21-22, 33-34, 50, and 52 remain rejected under 35 U.S.C. 102(b) as being anticipated by Berlin et al. for the reasons of record as set forth in the Office action mailed on January 6, 2010 and for the reasons stated below.

Applicant's arguments filed on May 11, 2010 have been fully considered but they are not persuasive. Applicant argues that the claims are not anticipated because the nucleic acid of

Berlin et al. is not "isolated from the genome of a virus". Applicant's attention is directed to the fact that the claims are drawn to a nucleic acid of 15-24 (or 18-24) nucleotides or a complement thereof, wherein the nucleic acid is 40.9% complementary to an mRNA. Further, when the "second" nucleic acid structural limitations are taken into consideration for determining patentability of the "first" nucleic acid, the 15-24 (or 18-24) nucleotides need to be only at least 30.8% complementary or homologous to SEQ ID NO:2079 (one of the "two stem segments" of the second nucleic acid). Berlin et al. disclosed a nucleic acid of 18 nucleotides in length (see SEQ ID NO:1247 or 1249) that is highly homologous and complementary to SEQ ID NO:2079. Further, they taught that SEQ ID NO:1247 or 1249 is capable of inhibiting target mRNA. Hence, the nucleic acid product of Berlin et al. is essentially identical to the claimed first nucleic acid, and thus, the nucleic acid of Berlin et al. must be inherently "viral" and must be present in a viral genome, absent evidence to the contrary. Again, the structural and functional limitations set forth for the claimed first nucleic acid are met by SEQ ID NO:1247 or 1249 of Berlin et al.

Note that when a rejection is based on a reference teaching a product appearing to be substantially identical to the claimed product, and when the examiner presents reasoning tending to show inherency, the burden shift to the applicant to show an unobvious difference. See MPEP 2112: "[T]he PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his [or her] claimed product. Whether the rejection is based on inherency under 35 U.S.C. 102, on *prima facie* obviousness under 35 U.S.C. 103, jointly or alternatively, the burden of proof is the same...[footnote omitted]."

Claims 21-22, 33-34, 50, and 52 remain rejected under 35 U.S.C. 102(b) as being anticipated by Baker et al. for the reasons of record as set forth in the Office action mailed on January 6, 2010 and for the reasons stated below.

Applicant's arguments filed on May 11, 2010 have been fully considered but they are not persuasive. Applicant argues that the claims are not anticipated because the nucleic acid of Baker et al. is not "isolated from the genome of a virus". Applicant's attention is directed to the fact that the claims are drawn to a nucleic acid of 15-24 (or 18-24) nucleotides or a complement thereof, wherein the nucleic acid is 40.9% complementary to an mRNA. Further, when the "second" nucleic acid structural limitations are taken into consideration for determining patentability of the "first" nucleic acid, the 15-24 (or 18-24) nucleotides need to be only at least 30.8% complementary or homologous to SEQ ID NO:2079 (one of the "two stem segments" of the second nucleic acid). Baker et al. disclosed a nucleic acid of 18 nucleotides in length (see SEQ ID NO:101) that is highly complementary to SEQ ID NO:2079. Further, they taught that SEQ ID NO:101 is capable of inhibiting target mRNA. Hence, the nucleic acid product of Bakeret al. is essentially identical to the claimed first nucleic acid, and thus, the nucleic acid of Baker et al. must be inherently "viral" and must be present in a viral genome, absent evidence to the contrary. Again, the structural and functional limitations set forth for the claimed first nucleic acid are met by SEQ ID NO:101 of Baker et al.

Note that when a rejection is based on a reference teaching a product appearing to be substantially identical to the claimed product, and when the examiner presents reasoning tending to show inherency, the burden shift to the applicant to show an unobvious difference. See MPEP 2112: "[T]he PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his [or her] claimed product. Whether the rejection is

based on inherency under 35 U.S.C. 102, on *prima facie* obviousness under 35 U.S.C. 103, jointly or alternatively, the burden of proof is the same...[footnote omitted]."

Claims 21-22, 33, 50, and 52 remain rejected under 35 U.S.C. 102(b) as being anticipated by Lieven et al. for the reasons of record as set forth in the Office action mailed on January 6, 2010 and for the reasons stated below.

Applicant's arguments filed on May 11, 2010 have been fully considered but they are not persuasive. Applicant argues that the claims are not anticipated because the nucleic acid of Lieven et al. is not "isolated from the genome of a virus". Applicant's attention is directed to the fact that the claims are drawn to a nucleic acid of 15-24 nucleotides or a complement thereof, wherein the nucleic acid is 40.9% complementary to an mRNA. Further, when the "second" nucleic acid structural limitations are taken into consideration for determining patentability of the "first" nucleic acid, the 15-24 nucleotides need to be only at least 30.8% complementary or homologous to SEQ ID NO:2079 (one of the "two stem segments" of the second nucleic acid). Lieven et al. disclosed a nucleic acid of 15 nucleotides in length (see SEQ ID NO:28) that is at highly homologous to SEQ ID NO:2079. Further, they taught that SEQ ID NO:28 is capable of inhibiting target mRNA. Hence, the nucleic acid product of Lieven et al. is essentially identical to the claimed first nucleic acid, and thus, the nucleic acid of Lieven et al. must be inherently "viral" and must be present in a viral genome, absent evidence to the contrary. Again, the structural and functional limitations set forth for the claimed first nucleic acid are met by SEQ ID NO:28 of Lieven et al.

Note that when a rejection is based on a reference teaching a product appearing to be substantially identical to the claimed product, and when the examiner presents reasoning tending

to show inherency, the burden shift to the applicant to show an unobvious difference. See MPEP 2112: "[T]he PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his [or her] claimed product. Whether the rejection is based on inherency under 35 U.S.C. 102, on *prima facie* obviousness under 35 U.S.C. 103, jointly or alternatively, the burden of proof is the same...[footnote omitted]."

Claims 21and 52 remain rejected under 35 U.S.C. 102(b) as being anticipated by Zhu et al. for the reasons of record as set forth in the Office action mailed on January 6, 2010 and for the reasons stated below.

Applicant's arguments filed on May 11, 2010 have been fully considered but they are not persuasive. Applicant argues that the claims are not anticipated because the nucleic acid of Zhu et al. exceeds 24 nucleotides in length, which is the maximum length limitation for the claimed first nucleic acid. Contrary to applicant's argument, the nucleic acid isolated from nucleotides 1010-1055 (see Figure 2) of RSV-T RNA 4 of Zhu et al. inherently possesses an "isolated" nucleic acid that is 21 nucleotides in length and its complement thereof, which is the subject matter claimed and thus meets the structural limitation for the claimed first nucleic acid. See the two stem sequences of the "isolated" viral nucleic acid, wherein either of the two stem sequences of 21 nucleotides in length is inherently and necessarily "isolated" and does not exceed 24 nucleotides in length. Again, since the entire nucleic acid of Figure 2 is isolated, the stem sequences of 21 nucleotides are inherently and necessarily isolated, absent evidence to the contrary.

Note that when a rejection is based on a reference teaching a product appearing to be substantially identical to the claimed product, and when the examiner presents reasoning tending

to show inherency, the burden shift to the applicant to show an unobvious difference. See MPEP 2112: "[T]he PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his [or her] claimed product. Whether the rejection is based on inherency under 35 U.S.C. 102, on *prima facie* obviousness under 35 U.S.C. 103, jointly or alternatively, the burden of proof is the same...[footnote omitted]."

Claims 21and 52 remain rejected under 35 U.S.C. 102(b) as being anticipated by Ghiringhelli et al. for the reasons of record as set forth in the Office action mailed on January 6, 2010 and for the reasons stated below.

Applicant's arguments filed on May 11, 2010 have been fully considered but they are not persuasive. Applicant argues that the claims are not anticipated because the nucleic acid of Chiringhelli et al. exceeds 24 nucleotides in length, which is the maximum length limitation for the claimed first nucleic acid. Contrary to applicant's argument, the nucleic acid isolated from Junin virus S RNA (see nucleotides 1582-1619 in Figure 6) of Ghiringhelli et al. inherently possesses an "isolated" nucleic acid that is 17-18 nucleotides in length and its complement thereof, which is the subject matter claimed and thus meets the structural limitation for the claimed first nucleic acid. See the two stem sequences of the "isolated" viral nucleic acid, wherein either of the two stem sequences of 17-18 nucleotides in length is inherently and necessarily "isolated" and does not exceed 24 nucleotides in length. Again, since the entire nucleic acid of Figure 6 is isolated, the stem sequences of 17-18 nucleotides are inherently and necessarily isolated, absent evidence to the contrary.

Note that when a rejection is based on a reference teaching a product appearing to be substantially identical to the claimed product, and when the examiner presents reasoning tending

to show inherency, the burden shift to the applicant to show an unobvious difference. See MPEP 2112: "[T]he PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his [or her] claimed product. Whether the rejection is based on inherency under 35 U.S.C. 102, on *prima facie* obviousness under 35 U.S.C. 103, jointly or alternatively, the burden of proof is the same...[footnote omitted]."

Claims 21and 52 remain rejected under 35 U.S.C. 102(b) as being anticipated by Baumstark et al. for the reasons of record as set forth in the Office action mailed on January 6, 2010 and for the reasons stated below.

Applicant's arguments filed on May 11, 2010 have been fully considered but they are not persuasive. Applicant argues that the claims are not anticipated because the nucleic acid of Baumstark et al. exceeds 24 nucleotides in length, which is the maximum length limitation for the claimed first nucleic acid. Contrary to applicant's argument, the nucleic acid isolated from BMV, CMV-1, CMV-II, and TAV (see Figures 7A-B) inherently possesses an "isolated" nucleic acid that is 15-24 nucleotides in length and its complement thereof, which is the subject matter claimed and thus meets the structural limitation for the claimed first nucleic acid. See the two stem sequences of the "isolated" viral nucleic acid, wherein either of the two stem sequences of 15-24 nucleotides in length is inherently and necessarily "isolated" and does not exceed 24 nucleotides in length. Again, since the entire BMV, CMV-1, CMV-II, and TAV nucleic acids of Figures 7A-7B are isolated, the stem sequences of 15-24 nucleotides are inherently and necessarily isolated, absent evidence to the contrary.

Note that when a rejection is based on a reference teaching a product appearing to be substantially identical to the claimed product, and when the examiner presents reasoning tending

to show inherency, the burden shift to the applicant to show an unobvious difference. See MPEP 2112: "[T]he PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his [or her] claimed product. Whether the rejection is based on inherency under 35 U.S.C. 102, on *prima facie* obviousness under 35 U.S.C. 103, jointly or alternatively, the burden of proof is the same...[footnote omitted]."

Claims 21and 52-53 remain rejected under 35 U.S.C. 102(b) as being anticipated by Ozdarendeli et al. for the reasons of record as set forth in the Office action mailed on January 6, 2010 and for the reasons stated below.

Applicant's arguments filed on May 11, 2010 have been fully considered but they are not persuasive. Applicant argues that the claims are not anticipated because the nucleic acid of Ozdarendeli et al. exceeds 24 nucleotides in length, which is the maximum length limitation for the claimed first nucleic acid. Contrary to applicant's argument, the nucleic acid isolated from nucleotides 1760-1803 (see Figure 2A) of Ozdarendeli et al. inherently possesses an "isolated" nucleic acid that is 17-18 nucleotides in length and its complement thereof, which is the subject matter claimed and thus meets the structural limitation for the claimed first nucleic acid. See the two stem sequences of the "isolated" viral nucleic acid, wherein either of the two stem sequences of 17-18 nucleotides in length is inherently and necessarily "isolated" and does not exceed 24 nucleotides in length. Again, since the entire viral nucleic acid of Figure 2A is isolated, the stem sequences of 17-18 nucleotides are inherently and necessarily isolated, absent evidence to the contrary.

Note that when a rejection is based on a reference teaching a product appearing to be substantially identical to the claimed product, and when the examiner presents reasoning tending

to show inherency, the burden shift to the applicant to show an unobvious difference. See MPEP 2112: "[T]he PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his [or her] claimed product. Whether the rejection is based on inherency under 35 U.S.C. 102, on *prima facie* obviousness under 35 U.S.C. 103, jointly or alternatively, the burden of proof is the same...[footnote omitted]."

Claims 21and 52-53 remain rejected under 35 U.S.C. 102(b) as being anticipated by Davison et al. for the reasons of record as set forth in the Office action mailed on January 6, 2010 and for the reasons stated below.

Applicant's arguments filed on May 11, 2010 have been fully considered but they are not persuasive. Applicant argues that the claims are not anticipated because the nucleic acid of Davison et al. exceeds 24 nucleotides in length, which is the maximum length limitation for the claimed first nucleic acid. Contrary to applicant's argument, the nucleic acid isolated from HSV-1 or VZV (see Figure 6) of Davison et al. inherently possesses an "isolated" nucleic acid that is about 20-21 nucleotides in length and its complement thereof, which is the subject matter claimed and thus meets the structural limitation for the claimed first nucleic acid. See the two stem sequences of the "isolated" viral nucleic acid, wherein either of the two stem sequences of 20-21 nucleotides in length is inherently and necessarily "isolated" and does not exceed 24 nucleotides in length. Again, since the entire HSV-1 and VZV nucleic acids of Figure 6 are isolated, the stem sequences of 20-21 nucleotides are inherently and necessarily isolated, absent evidence to the contrary.

Note that when a rejection is based on a reference teaching a product appearing to be substantially identical to the claimed product, and when the examiner presents reasoning tending

to show inherency, the burden shift to the applicant to show an unobvious difference. See MPEP 2112: "[T]he PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his [or her] claimed product. Whether the rejection is based on inherency under 35 U.S.C. 102, on *prima facie* obviousness under 35 U.S.C. 103, jointly or alternatively, the burden of proof is the same...[footnote omitted]."

Claim Rejections - 35 USC § 103

Claims 21-34, 50, and 52-53 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Lai et al., Zhu et al., Ghiringhelli et al., Baumstark et al., Ozdarendeli et al., Davison et al., and Perry et al. for the reasons of record as set forth in the Office action mailed on January 6, 2010 and for the reasons stated below.

Applicant's arguments filed on May 11, 2010 have been fully considered but they are not persuasive. Applicant argues that the claims are not obvious because the examiner has failed to show that "one of skill would have an expectation to succeed in this endeavor." to isolate miRNAs from the viral genomes because "miRNAs and hairpin precursors were believed to be present in only complex eukaryotes"; because the methodologies disclosed in Lai et al. are based on hairpins and miRNAs of eukaryotes; and because viral genomes contain little intergenic space to harbor hairpin structures. Contrary to applicant's argument, the purported reasons applicant is relying on for the likelihood of unsuccessful isolation of miRNAs from a viral genome do not show that one would not have had a reasonable expectation of success in arriving at the claimed subject matter. First, applicant's attention is directed to the fact that for obviousness under §103, "all that is required is a reasonable expectation of success", and it does not require "absolute predictability of success". See *In re O 'Farrell*, 853 F.2d 894, 7 USPQ2d 1673 (Fed. Cir. 1988)

at 1681. Second, contrary to applicant's alleged "absolutely no possibility of finding miRNAs in a viral genomic sequence", one would have reasonably predicted to find miRNAs within an intergenic region of a viral sequence at the time the instant application was filed because secondary structures satisfying the structural limitations set forth for the stem-loop precursor "second viral nucleic acid", which was explained by applicant that it contains the claimed "first viral nucleic acid" (see pages 7-8 of the reply filed on May 11, 2010) were known to be present in many different viral genomes as taught by Zhu et al., Ghiringhelli et al., Baumstark et al., Ozdarendeli et al., and Davison et al. Hence, applicant's statement that the intergenic regions of viral genomes are too small to contain secondary structures and thus one would have had "absolutely no possibility of finding miRNAs in a viral genomic sequence" merely amounts to an allegation unsupported by objective evidence. In addition, contrary to applicant's argument that the intergenic region must be large or long enough to contain miRNAs, Lai et al. taught that "miRNA genes reside in short regions of exceptional conservation, easily seen as local 'peaks' (Figure 1)." See page 2. Further, contrary to applicant's argument that one would not have used the eukaryote-based miRNA identification methodologies of Lai et al. in order to identify miRNAs present in the HSV-1 genomic sequence of Perry et al., one of ordinary skill in the art would have been reasonably and sufficiently motivated to apply the bioinformatics-based approach of Lai et al. in finding miRNAs present in the HSV-1 of Perry et al. because they taught that one can use their bioinformatics tool to discover unknown miRNAs "in a given sequenced genome" (see page 16) and did not exclude sequenced viral genomes as an exception to the rule. That is, there is no implicit or explicit teaching/suggestion in the Lai et al. reference that one cannot or should not use their computational, bioinformatics tool to identify unknown miRNAs in a given sequenced viral genome such as the HSV-1 genome of Perry et al. Hence,

one has no reason/motivation not to apply the miRNA identification methodologies of Lai et al. to identify miRNAs present in the already sequenced HSV-1 genome of Perry et al. Again, the mere fact that Lai et al. used their methodologies to identify eukaryotic miRNAs does not whatsoever indicate or suggest that their methodologies are inapplicable for identifying miRNAs present in a viral genome, and furthermore, Lai et al. explicitly suggested that their miRNA identification methodologies "might permit the unbiased discovery of the remaining complement of miRNA genes in a given sequenced genome." See page 16. Further, even if one chooses not to use the "miRseeker" program of Lai et al. *per se*, the teachings of Lai et al. provide sufficient guidance as to how one can identify potential miRNA sequences within a given sequence genome and how one can verify that the potential miRNA sequences are indeed miRNA genes. For example, they taught that all of the stem-loop miRNA precursor sequences (*Drosophilia, Caenorhabditis,* mice, humans, plants) identified thus far are usually around 70-100, 70-120, 70-150 nucleotides in length and that all of miRNAs are about 21-24 nucleotides in length and located in untranslated regions as they are non-coding small RNAs. They also taught that one can utilize RNA folding programs to predict whether the potential sequences yield secondary structures predicted of miRNA precursors. They also taught that one can verify whether the potential, putative miRNAs are indeed genuine miRNA genes by performing northern analysis. In addition, Lai et al. taught that one can further use concurrent genomic analyses provided by citation numbers 31-34 (see page 2), wherein citation number 32, the Lim et al. reference (*Genes & Development,* 2003, 17:991-1008) in fact teaches that the RNA structure prediction method disclosed in Hofacker et al. (*Nucleic Acids Research,* 1998, 26:3825-3836) was used in order to search for potential *C. elegans* miRNA hairpins. Note that the teachings of Hofacker et al. relate to predicting RNA hairpin or stem-loop secondary structures in virus genomes. Given such

knowledge and information pertaining to miRNA precursors and miRNA genes available at the time of filing, further in view of the fact that many stem-loop secondary structures have been known to be contained within a non-coding region of a viral genomic sequence, and further in light of the fact that prediction methods for secondary RNA structure in viral genomes were known and such methods were utilized and incorporated in identifying *C. elegans* miRNA hairpin structures, one of ordinary skill in the art would have had a reasonable, if not absolute, expectation of success in identifying a precursor secondary structure in the HSV-1 genome as well as verifying the nucleotide sequence of "UGGAAGGACGGGAAGUGGAAGU" located nucleotides 118330-118351 within the non-coding intergenic region of the HSV-1 genomic sequence of Perry et al. as a genuine miRNA gene present in the HSV-1 genomic sequence. That is, the likelihood of success in identifying SEQ ID NO:2079 claimed in the instant case as a miRNA sequence in the HSV-1 genomic sequence would have been more probable than not in view of the totality of the combined teachings of the prior art cited herein.

Further, in response to applicant's assertion that "miRNAs and hairpin precursors were believed to be present in only complex eukaryotes" at the time of filing, applicant's attention is directed to the fact that applicant's such assertion is not fact-based. For example, it was known in the art, at the time of filing, that about 50-200 non-coding hairpin precursor-structured RNAs are present in *E. coli,* wherein such RNAs repress target mRNA translation. Further, using computation-based searches for identifying non-coding RNAs in yeast cells (*S. cerevisiae)* and bacteria cells (*E. coli*) and other single-cell microorganisms (*M. jannaschii,P. furiosus*) based on known properties of non-coding RNAs (e.g., intergenic regions, RNA secondary structures) was routine. See for example Storz (*Science,* 2002, 296:1260-1263). Further, Storz also teaches that non-coding stRNA (small temporal, stem-loop precursor RNA) and its product miRNA were

known to repress mRNA translation and be expressed at specific time points just like the non-coding RNAs of *E. coli.* In addition, non-coding regions of many viral genomes were known to contain secondary fold-back, hairpin structures as taught by Zhu et al., Ghiringhelli et al., Baumstark et al., Ozdarendeli et al., Davison et al., Yu et al. (*Journal of Virology,* 1999, citation of record), and Knonings et al. (*Journal of Virology,* 1992, citation of record), As such, there is no scientific reason for one to believe that stRNAs (miRNA hairpin precursors) or miRNAs are exclusively present "in only complex eukaryotes" as alleged by applicant. Note that the arguments of counsel cannot take the place of evidence in the record. See MPEP 2145: "An assertion of what seems to follow from common experience is just attorney argument and not the kind of factual evidence that is required to rebut a prima facie case of obviousness." Also See *Ex parte Webb*, 30 USPQ2d 1064, 1067-68 (Bd. Pat. App. & Int.1993): "it is incumbent upon applicant to come forth with countervailing evidence to rebut the rejection made by the examiner."

Applicant argues that the predicted frequency of hairpins for HSV-1 would have been less than 1 at the time of filing and therefore "one of ordinary skill in the art would have not expected to be able to identify miRNAs and hairpin precursors in viruses regardless of the method of identification and HSV-1 does not dispel this notion." First, applicant has relied on the postulation that the frequency of a hairpin precursor occurs, on average, every 1.80×10^7 bp of the genome. However, applicant has merely relied on the "reported" number of hairpin precursors in the "Sanger" database at the time of filing in order to deduce the "every 1.80×10^7 bp of the genome" formula. Hence, applicant states that for humans, there are 176 reported hairpins at the time of filing. See Table 1 at page 13 of the reply filed on February 26, 2008. It is noted that examiner cannot verify applicant-provided information that there were indeed 176

reported hairpins at the time of filing, and furthermore, even if it is true that there were 176 reported hairpins in the Sanger database for human genome at the time of filing, the Sanger database does not accurately represent the state of the art at the time of filing. For example, Lai et al. taught, at the time of filing, that nearly 1% of human genome is predicted to be miRNA genes. See page 16. Similarly, Lim et al. (*Science,* 2003, citation of record, applicant's citation) taught that the human genome is estimated to contain about 200-255 miRNA genes, in contrast to 176 hairpin structures in the human genome as asserted by applicant. Further, Lai et al. estimated, at the time of filing, that the *Drosophila* genome contains around 110 miRNA genes (see page 2), whereas applicant has asserted that there were 78 reported hairpins at the time of filing. In addition, applicant has asserted that there were 106 reported hairpin structures in the *C. elegans* genome at the time of filing. However, it was estimated in the art, at the time of filing, that the *C. elegans* genome encodes 140-300 miRNAs and potentially more (e.g., hundreds to thousands) as taught by Grad et al. (*Molecular Cell,* 2003, citation of record) and Storz (*Science,* 2002, 296:1230-1263). Hence, the number of hairpins listed in Table 1 or Table 3 is considerably less than the number of miRNA genes (the claimed subject matter) predicted and estimated by the researchers in the art at the time of filing. Furthermore, with regard to the presence/frequency of generic "hairpin structures" (not necessarily those containing miRNA genes) within a viral genome sequence as predicted by applicant, it was shown that the bovine coronavirus (BCoV) genome sequence contains more than one stabilized stem-loop structures in the non-coding region as taught by Ozdarendeli et al. See Figure 2A. Similarly, it was shown that bovine viral diarrhea virus genome sequence contains more than one hairpin secondary structures in the non-coding region as taught by Yu et al. (*Journal of Virology,* 1999, citation of record). See Figure 4A. See also Konings et al. (*Journal of Virology,* 1992, citation of record), who taught that the 5'

UTR of 16 of MLV-related type C viruses contains at least two hairpin structures. See Figure 4. In addition, it was known in the art many members (e.g., HCV, GBV-B, BVDV, HoCV) of the *Flaviviridae* family contain phylogenetically conserved stem-loop secondary structures in the 5' non-translated region. See Honda et al. (*Journal of Virology,* 1999, 73:1165-1174). Moreover, it was known that HCV and HIV1 genomes contain 10 or more stem-loop secondary structures including in non-coding regions. See Hofacker et al. (*Nucleic Acids Research,* 1998, 26:3825-3836), who also show that hantavirus contains a stem-loop or hairpin precursor secondary structure as depicted in Figure 10. Hence, applicant's assertion that one can only find, at best, less than one hairpin structure (e.g., 0.186 for EBV; 0.243 for HCMV; 0.00839 for HPV; and 0.161 for HSV-1) within a given viral genome is not universally applicable to all viral genomes. Further, as explained hereinabove, applicant's postulated number of generic "hairpins" reported at the time of filing is considerably lower than the reported number of miRNA genes (the claimed subject matter) at the time of filing. As such, one cannot rely on the "prediction" schemes provided by applicant (see Tables 1-4 in the reply filed on February 26, 2008 and the Table at page 15 of the reply filed on May 11, 2010) in order to reasonably predict the number/frequency of generic hairpin structure or miRNA genes as they are not verified to be accurate by any measure. Hence, there is no reason to believe that applicant's postulated number/frequency of hairpin structures for a given viral genome sequence is correct, nor is there a scientific reason to establish a "reasonable expectation of success" or "reasonable predictability" based on the applicant-derived methodology. Again, note that applicant-provided numbers of hairpin structures at the time of filing, especially for humans, *Drosophila,* and *C. elegans,* are considerably lower than the number of miRNA genes predicted/estimated for each organism at the time of filing. Further, note that non-coding regions of a viral genome were

known to contain more than one hairpin structures at the time of filing. In particular, it was known in the art that an HSV-1 intergenic region contains a hairpin structure at nucleotides 2415-2459 as taught by Davison et al., and therefore, it was known that HSV-1 contains at least 1 (thus more than 0.00844-0.161 predicted by applicant) hairpin structure in the non-coding region of the HSV-1 genomic sequence. In addition to the hairpin structure located at nucleotides 2415-2459 in the HSV-1 genome as taught by Davison et al., it was also known that the intronic, non-coding LAT of the HSV-1 contains at least one hairpin structure as taught by Thomas et al. (*Journal of Virology,* 2002, 76:532-540). As such, applicant's assertion that one has, at best, only about 0.161 frequency for finding hairpin structures within the HSV-1 genomic sequence, and thus "less than one (1) hairpin precursor would have been expected to be present" amounts to a mere allegation unsupported by scientifically grounded or validated evidence. Again, the scientific fact that more than one hairpin structures are present in the HSV-1 genome indicates that applicant's assertion that one would have expected to observe "less than one miRNA/hairpin per genome" is merely based on applicant-devised system of estimating hairpin structure frequencies but not supported by scientific evidence.

In view of the foregoing, since applicant's arguments are not persuasive to show the alleged "unpredictability" or the alleged "no reasonable expectation" or the asserted nonobviousness of the claims in view of the totality of the teachings of the combination of the prior art references and the state of the art/technology disclosed by the references, this rejection is maintained.

Double Patenting

Claims 21, 33-34, and 52-53 remain rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6 of U.S. Patent No. 7,696,334 (Application No. 10/604,942) for the reasons of record as set forth in the Office action mailed on January 6, 2010 and for the reasons stated below.

Applicant's arguments filed on May 11, 2010 have been fully considered but they are not persuasive. Applicant has stated: "Applicant submits a terminal disclaimer of the instant application signed by an authorized agent of the assignee to the '334 patent in compliance with 37 C.F.R. §1.321(c) and 37 C.F.R. §3.73(b) thereby overcoming the alleged nonstatutory double patenting rejection." However, examiner was unable to locate any signed terminal disclaimer as alleged by applicant. Hence, this rejection is maintained.

Claims 21, 33-34, and 52-53 remain rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6 of U.S. Patent issuing from Application No. 10/604,943 for the reasons of record as set forth in the Office action mailed on January 6, 2010 and for the reasons stated below.

Applicant's arguments filed on May 11, 2010 have been fully considered but they are not persuasive. Applicant has stated: "Applicant submits a terminal disclaimer of the instant application signed by an authorized agent of the assignee to the '943 patent application in compliance with 37 C.F.R. §1.321(c) and 37 C.F.R. §3.73(b) thereby overcoming the alleged nonstatutory double patenting rejection." However, examiner was unable to locate any signed terminal disclaimer as alleged by applicant. Hence, this rejection is maintained.

Claims 21, 33-34, and 52-53 remain rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6 of U.S. Patent No. 7,696,342 (Application No. 10/604,945) for the reasons of record as set forth in the Office action mailed on January 6, 2010 and for the reasons stated below.

Applicant's arguments filed on May 11, 2010 have been fully considered but they are not persuasive. Applicant has stated: "Applicant submits a terminal disclaimer of the instant application signed by an authorized agent of the assignee to the '342 patent in compliance with 37 C.F.R. §1.321(c) and 37 C.F.R. §3.73(b) thereby overcoming the alleged nonstatutory double patenting rejection." However, examiner was unable to locate any signed terminal disclaimer as alleged by applicant. Hence, this rejection is maintained.

Claims 21, 33-34, and 52-53 remain rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6 of U.S. Patent No. 7,759,478 (Application No. 10/604,984) for the reasons of record as set forth in the Office action mailed on January 6, 2010 and for the reasons stated below.

Applicant's arguments filed on May 11, 2010 have been fully considered but they are not persuasive. Applicant has stated: "Applicant submits a terminal disclaimer of the instant application signed by an authorized agent of the assignee to the '984 patent application in compliance with 37 C.F.R. §1.321(c) and 37 C.F.R. §3.73(b) thereby overcoming the alleged nonstatutory double patenting rejection." However, examiner was unable to locate any signed terminal disclaimer as alleged by applicant. Hence, this rejection is maintained.

Claim 53 remains rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 2 of U.S. Patent No. 7,217,807 B2 for the reasons of record as set forth in the Office action mailed on January 6, 2010 and for the reasons stated below.

Applicant's arguments filed on May 11, 2010 have been fully considered but they are not persuasive. Applicant has stated: "Applicant submits a terminal disclaimer of the instant application signed by an authorized agent of the assignee to the '807 patent in compliance with 37 C.F.R. §1.321(c) and 37 C.F.R. §3.73(b) thereby overcoming the alleged nonstatutory double patenting rejection." However, examiner was unable to locate any signed terminal disclaimer as alleged by applicant. Hence, this rejection is maintained.

Claims 21, 33-34, and 52-53 remain rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6 of U.S. Patent issuing from Application No. 10/709,739 for the reasons of record as set forth in the Office action mailed on January 6, 2010 and for the reasons stated below.

Applicant has not provided any rebuttal arguments addressing the supposed errors of this rejection, nor has applicant filed a signed terminal disclaimer. Hence, this rejection is maintained.

Claims 21, 33-34, and 52-53 remain rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6 of U.S. Patent issuing from Application No. 11/511,035 for the reasons of record as set forth in the Office action mailed on January 6, 2010 and for the reasons stated below.

Applicant has not provided any rebuttal arguments addressing the supposed errors of this rejection, nor has applicant filed a signed terminal disclaimer. Hence, this rejection is maintained.

Claims 21, 33-34, and 52-53 remain provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 26-28 of Application No. 12/517,760 for the reasons of record as set forth in the Office action mailed on January 6, 2010 and for the reasons stated below.

Applicant has not provided any rebuttal arguments addressing the supposed errors of this rejection, nor has applicant filed a signed terminal disclaimer. Hence, this rejection is maintained.

Conclusion

No claim is allowed.

This application contains claims 35-48, 51, and 54-55 drawn to an invention nonelected with traverse in the reply filed on August 18, 2008. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DANA SHIN whose telephone number is (571)272-8008. The examiner can normally be reached on Monday through Friday, 7am-3:30pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low (Acting SPE) can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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